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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,569	08/20/2001	Thomas Wild	9793/97	5757

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EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,569

Applicant(s)

WILD ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 12, 14, 15, 17-19, 21-23, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-12, 14-15, 17-19, 21-23, 25-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The Amendment filed May 17, 2004 in response to the Office Action of January 14, 2004 is acknowledged and has been entered. Previously pending claims 13, 16, 20 and 24 have been cancelled, claims 11-12, 14-15, 17-19, 21-23 and 26 are pending, claim 14 have been amended.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made..

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-12, 14-15, 17-19, 21-23, 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over (USP#4,228,237) in view of O'Connell et al (USP#4,693,970).

Hevey et al teaches methods for the detection and determination of ligands utilizing a biotin/avidin system. Claims 11-14 and 17-19 teach several embodiments of assay and methods that determine the presence and amount of a ligand. One embodiment teaches an enzyme coated avidin (assay component) bound to a biotin (1st hapten) labeled reagent that comprise of a specific binding substance (analyte specific component) for the determination of a ligand. The specific binding substance (analyte specific component) is specific for binding the ligand in the assay (see summary, lines 1-50). The ligand in this embodiment exhibits binding specificity to the specific binding substance (analyte specific component) and the exclusion of other substance in the assay (col. 4, lines 31-36). Hevey et al teaches that when the ligand is a hapten, a specific binding substance utilized to detect the hapten is an antibody produced when the hapten, bound to an antigenic carrier is introduced into a sample (col. 4, lines 61-65). Hevey et al teaches that during the binding steps, the reagents may be incubated individually or in particular sequence, as taught in claims 11, 17-18 (col. 2, lines 58-62). The reaction is measured by the activity of the enzyme labeled avidin (col. 3, lines 64-68 & col. 4, lines 1-5). Examples of solid carriers used in this invention range from microtiter plates to nylon beads (col. 5, lines 32-41). HRP labeled avidin is pre-reacted with biotin labeled antibody, which is added to the insoluble phase

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after the antigen has been incubated as taught in claim 26 (col. 9, lines 29-35). In a non-competitive binding process, the insoluble phase may be incubated with the reagents together in the presence of one another, as taught in claim 25 (col. 2, lines 58-62). With respect to hapten being identical, Hevey et al discloses that each reagent of the assay are used in excess column 10, lines 40-56 and column 13, claims 25-28). It is the Examiner's position that biotin (1st hapten) used in excess will saturate binding sites of the specific binding substance (analyte specific component) and the remaining excess biotin (2nd hapten) will bind the avidin (assay component); therefore, the teaching of identical haptens, are taught by Hevey et al.

The instant claims are further drawn to a homogeneous assay format.

Hevey et al does not teach a homogeneous binding assay.

However, O'Connell teaches that homogeneous assays do not require a separation step and thereby provide significant advantages in speed, convenience and ease of automation over heterogeneous assays (column 1, lines 23-28).

It would have been obvious to one of ordinary skill in the art to modify the teaching of Hevey et al to include performing the instant assay in a homogeneous format because it requires no separation of reagents and therefore provides the advantages of speed and convenience over the heterogeneous assays.

Response to Arguments

3. Applicant argues that the reference of Hevey et al does not teach a homogeneous assay and only discloses heterogeneous formats.

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In response to applicant's arguments with respect to the limitation "homogeneous" have been considered but are moot in view of the new ground(s) of rejection that addresses that limitation above.

Applicant argues that the previous Office Action interpretation of the Hevey et al reference that biotin (1st hapten) used in excess will saturate binding sites of the specific binding substance (analyte specific component) and the remaining excess biotin (2nd hapten) will bind the avidin (assay component) is an incorrect scenario that describes the relationship of the biotin to the specific binding substance. Applicant further contends that Hevey et al discloses that the specific binding substance is labeled with, not bound to, the biotin, and that the specific binding substance of Hevey et al binds specifically to the ligand, which is the analyte. Applicant contends that biotin does not occupy the binding sites of the specific binding substance, but rather is linked to the specific binding substance in such a way that the specific binding substance is still available to bind the ligand.

In response to applicant argument that biotin does not occupy the binding sites of the specific binding substance in such a way that it is still available to bind the ligand, is a teaching is not prohibited by the instant claims. In response to applicant argument that biotin labeled specific binding substance taught by Hevey et al is not an independent hapten but only a label is not found persuasive because using a hapten as a label is not prohibited in the claims, further, according to applicant's specification, (page 5, lines 6-13) the hapten or hapten-like molecule can be a labeled detection

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reagent such as a labeled antibody that is used to mediate binding between the antibody and the analyte, which is a teaching disclosed by the Hevey et al.

Applicant's argument that Hevey et al does not teach a second hapten or hapten-like molecule that is not linked to an analyte specific component and therefore fail to anticipate because all the elements in the claims are not taught is not found persuasive.

In response to applicant's argument, Hevey et al teaches that biotin, which is the first hapten is used in excess. When biotin is used in excess, the remaining biotin, which is the second hapten will bind to avidin, which is the assay component taught in the claims. Hevey et al teaches that haptens in this assay can be prepared by covalent linkage or bridging molecules (column 5, lines 65-68 and column 6, line 1). This satisfies the limitation that the first hapten is linked to the analyte specific component and the second hapten which is in excess, is not linked to the analyte specific component but to the avidin which is the assay component. Therefore, it is the examiner's position that the teachings of Hevey et al teaches the instant claimed invention.

Conclusion

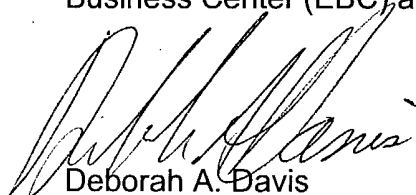
4. No claims are allowed.
5. All other objections and rejections imposed in the previous Office Action mailed January 14, 2004 are hereby withdrawn.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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July 19, 2004



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